(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 399 857 B1**

(12) # EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification: **02.08.95** (51) Int. Cl.[6]: **A61M 37/00**, B32B 25/10

(21) Application number: **90400840.6**

(22) Date of filing: **28.03.90**

(54) **Multilayer membrane for an implantable reservoir.**

(30) Priority: **28.03.89 FR 8903998**

(43) Date of publication of application:
28.11.90 Bulletin 90/48

(45) Publication of the grant of the patent:
02.08.95 Bulletin 95/31

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(56) References cited:
EP-A- 0 230 747
EP-A- 0 260 081
DE-A- 2 855 694
FR-A- 2 125 127
US-A- 3 922 468
US-A- 4 738 657

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EP 0 399 857 B1

Description

BACKGROUND OF THE INVENTION

The present invention relates to a membrane intended to close and form part of the external wall of a reservoir which is capable of being implanted under the skin of a patient. The membrane may also be used elsewhere as desired, wherever strength and flexibility are needed.

Such reservoirs are well-known, for example see French Patent Publication No. 2,582,222. These reservoirs are generally made of a hollow, rigid body closed by one or two membranes defining, with the body, a chamber of variable volume.

At least one other membrane or other barrier, typically of smaller size than the closure membrane, is generally mounted on the body in addition to the preceding membrane or membranes, to provide an injection site for filling the reservoir.

Also, a pump with manual, electronic, or electromechanical control allows a dose of the liquid contained in the reservoir to be transferred to a catheter which terminates at a predetermined site in the body of the patient.

When the assembly has been implanted under the skin of the patient, with the closure and filling membranes on the exterior side, the reservoir may be regularly filled using an injection syringe, the needle of which is successively caused to pass through the patient's skin and the membrane of the injection site.

Once the reservoir is filled, the patient can then himself deliver the medicament contained in the reservoir to the chosen site, with the aid of the pump.

It is, however, essential that the person carrying out the filling of the reservoir penetrates the injection site membrane, and not a closure membrane of the reservoir or a pump control.

On the other hand, EP-A-0 230 747 discloses an implantable infusion part comprising a base portion having a reinforcing layer made of a reinforcing sheet material such as nylon fabric embeded therein to enable the infusion part to be effectively secured to the tissue in the body of a patient by passing sutures through the base portion.

The present invention aims to the use of a membrane to prevent the penetration by a hypodermic needle, and nevertheless retaining all the characteristics required of such a membrane, for example its flexibility, allowing variation in the volume of the chamber. Also, the use of a membrane according to this invention can prevent diffusion of substances of low molecular weight, and exhibits good biocompatibility.

DESCRIPTION OF THE INVENTION

For this purpose, the invention provides with the use of a membrane according to claim 1.

The fibrous material may comprise polyaramide fibers such as those sold under the brand Kevlar by the Dupont de Nemours company, or alternatively, carbon, metal, or other fibers.

These fibers can be presented in one or several distinct layers, as desired.

The biocompatible elastomer layers can, for example, each comprise a layer of silicone or polyurethane.

Such a reinforced membrane then cannot be accidentally perforated, but nevertheless it retains the flexibility necessary for the variation of the reservoir volume. This membrane also allows the maximum capacity of the reservoir to be increased without risk, since it is of great strength and is thus exceedingly unlikely to rupture.

The fibrous material is preferably woven, and stabilized in a layer of resin to bind crossing fibers together. The regularity of the fibre network is thus assured. In addition, the resin prevents the fibers of the network from moving apart to allow the passage of a needle.

The resin can be any suitable type, for example an epoxy resin or a polyamide resin.

Advantageously, provision is made, in addition, to provide a water-excluding film between the layer of fibrous material and one of the biocompatible elastomer layers. This film is to give the membrane a good ability to exclude substances of low molecular weight such as water vapor. Among others, polyethylene, polyaramide, polyamide or polyester films may be used for this purpose. Biaxially oriented polyester films, for example those sold under the brand Mylar by the Dupont de Nemours Company, are currently preferred.

In order to allow better adhesion between the water-excluding film and the resin which stabilizes the fibrous material, another elastomer layer can be provided between the resin and the water-excluding film. A bonding primer may optionally be used to improve the adhesion.

A particular method of implementation of the invention will now be described as a non-limiting example, with reference to the drawings attached.

DESCRIPTION OF DRAWINGS

Fig. 1 is a schematic view of a membrane according to the invention in transverse section;

Fig. 2 is a greatly enlarged view of Fig. 1, taken in section along line II-II of Fig. 1;

Fig. 3 is a sectional view of an implantable pump and reservoir using the membrane of Figs. 1 and 2; and

Fig. 4 is a perspective view of the implantable pump and reservoir of Fig. 3.

DESCRIPTION OF SPECIFIC EMBODIMENTS

The membrane 10 represented in the drawings is a multilayer composite comprising, successively from the exterior 12 to the interior 8 of the reservoir 14, a layer of biocompatible silicone 1, a layer of epoxy resin 2, a cloth 3 of one or more layers of woven Kevlar fibers 16, a second layer 4 of epoxy resin, an optional intermediate flexible adhesive silicone layer 5, Mylar plastic film 6, and a third layer of biocompatible silicone 7. Layers 1, 5 and 7 are preferably elastomers, and may be polyurethane or the like as a substitute for silicone, if desired.

Layer 1 ensures biocompatibility with respect to the body of the patient, while layer 7 ensures biocompatibility with respect to the product contained in the interior 8 of the implanted reservoir 14.

The resin layers 2 and 4 are bonded to cloth 3, to ensure its stability, preventing its filaments 16 from moving apart. For example, an epoxide or polyimide resin is preferred for use as the filament stabilization resin in layers 2 and 4.

It would also be possible, instead of using two layers 2 and 4 and the cloth 3, to use a pre-impregnated cloth directly, in which filaments 16 are bonded together by a resin primer (such as epoxy) at their crossing points. This type of fabric has the advantage of being capable of being preformed and then directly injection-moulded with silicone layer 1. Such a pre-impregnated cloth is sold, for example, by the French company Brochier.

The intermediate silicone elastomer layer 5 allows bonding with the Mylar film 6 to be ensured, restricting or preventing diffusion of substances contained in the reservoir 8 through membrane 10.

As an example, the Kevlar cloth 3 used can be a satin, woven with filaments 16 of the order of 0.3 mm. in diameter, the distance between filaments being on the order of 0.1 mm., to prevent perforation of the membrane by a standard needle.

The silicone layers 1, 5 and 7 can have a thickness on the order of 0.5 mm., and the whole of the epoxy layers 2 and 4, and the cloth 3, can together have a thickness on the order of 0.5 mm..

The applicant has thus constructed a membrane giving satisfactory results by cold-forming of a Kevlar cloth, optionally pre-impregnated with epoxy resin, and curing and after-baking this pre-impregnated cloth.

Silicone elastomer layers 2, 5 may then each be moulded onto one side of the epoxy impregnated fabric 2, 3, 4 using an injection press, at 300 bars and 150 °C.

Thin Mylar plastic film 6 may be glued to the other side, after adding optional layer 5, when used, after which another moulding or extrusion 7 of silicone elastomer may be carried out to cover the Mylar plastic film 6.

Referring particularly to Figs. 3 and 4, an implantable, hand-operable dispenser for fluid medicaments is disclosed, which dispenser defines a reservoir portion 14 in which the interior 8 thereof is partially defined by membrane 11a as shown in Figs. 1 and 2 and described above. Membrane 11a is tough and resistant to a needle puncture or other rough handling.

The specific design of implantable dispenser which is disclosed here is described in detail in De Vries et al. U.S. Patent No. 4,668,231, issued May 26, 1987, the disclosure of which is incorporated by reference herein. The dispenser which is shown in Figs 3 and 4 may be made in accordance with the teachings of that cited patent, subject to the modifications as described herein.

As taught in the previously described patent, the dispenser describes not only a reservoir portion 14, but also a fluid dispensing portion 20, the two portions being connected together and coacting with each other. Fluid dispensing portion includes a pair of resilient pads 27, 37 which, after implantation of the dispenser in the human body, may be manually manipulated by pressing the overlying skin of the body with the fingers, to cause dispensing of a metered amount of fluid from reservoir interior 8 through tube 18 when the respective pads 27, 37 are pressed in proper order, as described in the cited patent.

In accordance with this invention, additional pieces of the membrane 11b of this invention may be attached to the respective pads 27, 37 to prevent hypodermic needle penetration from outside the skin through the pads 27, 37, because the membrane of this invention, as previously described, can be impervious to hypodermic needle penetration.

Domed pad 10, as shown in Figs. 3 and 4, may serve as a supply port, being penetrable by a hypodermic needle passing through the skin and then through the domed pad 10, to provide resupply medicament to the interior of reservoir 8. Since no membrane 11 covers domed pad 10, it is penetrable by a hypodermic needle. Thus, it is not possible to damage the dispensing device by an erroneous attempt to inject resupply medicament with the needle wrongly placed. If the needle is not placed to penetrate the skin and then domed pad 10, it cannot penetrate the dispensing device at all. Housing portion 22 may be made of a hard plastic which is also resistant to needle penetration.

Hence, the dispensing device may be safely and conveniently operated, while the flexible membranes 11a and 11b used in the device protect against needle puncture, while being flexible to permit the manipulation of pads 27, 37, and the necessary expansion and contraction of reservoir interior 8, as the volume of fluid therein is increased or decreased.

It is contemplated that the membrane 11 of this invention may be used in any other design of dispenser for fluid medicaments which is implantable into the human body, as well as in the specific design shown herein. The membrane of this invention may also be used to cover or define any site or area which should be flexible, yet which must be protected from any accidental hypodermic needle penetration. Likewise, the membrane of this invention may be used in any circumstance, in the medical field or elsewhere, where flexibility coupled with strength, and particularly resistance to penetration by a hypodermic needle, is desired. Particularly, the membrane of this invention makes possible the use of an implantable dispenser in which a needle-pierceable fluid resupply port 10 is on the same side of the dispenser as the reservoir membrane 11a. With the membrane, the risk is eliminated of an accidental puncturing of the reservoir by a misdirected needle.

Claims

1. Use of a membrane (11a) comprising at least one layer of a fibrous material arranged between a pair of layers of a biocompatible elastomer forming at least a portion of the external wall of a body-implantable dispenser for a fluid medicament, the density and the orientation of the fibre network being such that a needle cannot cross it with normal pressures, and the thickness of the fibers being such that they can resist the pressure which may be imposed by the point of a needle, to prevent the penetration of said portion by a hypodermic needle.

2. Use of a membrane according to claim 1, in which the fibrous material is a fabric made of polyaramide fibers.

3. Use of a membrane according to claims 1 and 2, in which said biocompatible elastomer layers are made of silicone.

4. Use of a membrane according to claims 1 to 3, including as a layer of said membrane a water-excluding film.

5. Use of a membrane according to claim 4, in which said water excluding film is a biaxialy oriented polyester material.

6. Use of a membrane according to claims 4 and 5, comprising a layer of silicon elastomer between said water-excluding film and said fibrous material.

7. Use of a membrane according to claims 1 to 6, in which said fibrous material is embedded in a bonding resin to secure crossing strands of said fibrous material in immovable relationship.

8. Use of a membrane according to claim 7, in which said resin is an epoxy resin.

Patentansprüche

1. Verwendung einer Membran (11a), die mindestens eine Schicht aus einem Fasermaterial, die zwischen einem Paar von Schichten aus einem physiologisch unbedenklichen Elastomer angeordnet ist, umfaßt und wenigstens einen Teil der Außenwand einer in den Körper implantierbaren Abgabevorrichtung für ein flüssiges Medikament bildet, wobei die Dichte und die Ausrichtung des Fasernetzwerks derart ist, daß eine Nadel dieses bei normalem Druck nicht durchstoßen kann, und die Dicke der Fasern derart ist, daß sie dem von der Spitze einer Nadel ausgeübten Druck standhalten können, um eine Durchdringung des genannten Teils durch eine subkutane Nadel zu verhindern.

2. Verwendung einer Membran nach Anspruch 1, bei welcher das Fasermaterial ein Gewebe aus Polyaramidfasern ist.

3. Verwendung einer Membran nach Anspruch 1 und 2, bei welcher die genannten Schichten aus einem physiologisch unbedenklichen Elastomer aus Silicon hergestellt sind.

4. Verwendung einer Membran nach Anspruch 1 bis 3, die als eine Schicht der genannten Membran einen wasserundurchlässigen Film einschließt.

5. Verwendung einer Membran nach Anspruch 4, bei der diese wasserundurchlässige Faser ein biaxial ausgerichtetes Polyestermaterial ist.

6. Verwendung einer Membran nach den Ansprüchen 4 und 5, die zwischen dem genannten wasserundurchlässigen Film und dem genannten Fasermaterial eine Schicht aus einem Sili-

conelastomer aufweist.

7. Verwendung einer Membran nach den Ansprüchen 1 bis 6, bei welcher das genannte Fasermaterial in einem Harz-Bindemittel eingebettet ist, um die sich kreuzenden Stränge des Fasermaterials zu immobilisieren.

8. Verwendung einer Membran nach Anspruch 7, bei welcher das genannte Harz ein Epoxidharz ist.

Revendications

1. Utilisation d'une membrane (11A) comprenant au moins une couche d'un matériau fibreux disposée entre une paire de couches d'un élastomère biocompatible formant au moins une partie de la paroi externe d'un distributeur de médicament liquide implantable dans le corps, la densité et l'orientation du réseau de fibres étant telle qu'une aiguille ne peut pas la traverser avec des pressions normales, et l'épaisseur des fibres étant telle qu'elles peuvent résister à la pression qui peut leur être imposée par la pointe d'une aiguille, afin d'éviter la pénétration de ladite partie par une aiguille hypodermique.

2. Utilisation d'une membrane selon la revendication 1, dans laquelle le matériau fibreux est un tissu en fibres polyaramide.

3. Utilisation d'une membrane selon les revendications 1 et 2, dans laquelle les couches d'élastomère biocompatible sont en silicone.

4. Utilisation d'une membrane selon les revendications 1 à 3, comprenant en tant que couche de ladite membrane, un film étanche à l'eau.

5. Utilisation d'une membrane selon la revendication 4, dans laquelle ledit film étanche à l'eau est un matériau polyester orienté biaxialement.

6. Utilisation d'une membrane selon les revendications 4 et 5, comprenant une couche d'élastomère silicone entre ledit film étanche à l'eau et ledit matériau fibreux.

7. Utilisation d'une membrane selon les revendications 1 à 6, dans laquelle ledit matériau fibreux est noyé dans une résine de liaison pour fixer les brins se croisant dudit matériau fibreux dans une relation inamovible.

8. Utilisation d'une membrane selon la revendication 7, dans laquelle ladite résine est une résine époxy.

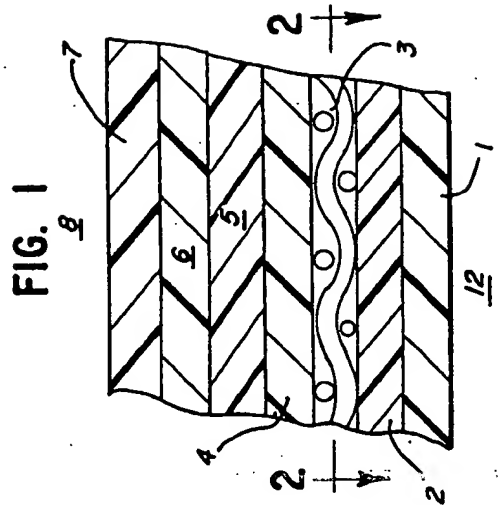
FIG. 1
8
7
6
5
3
1
12
4
2
2
2

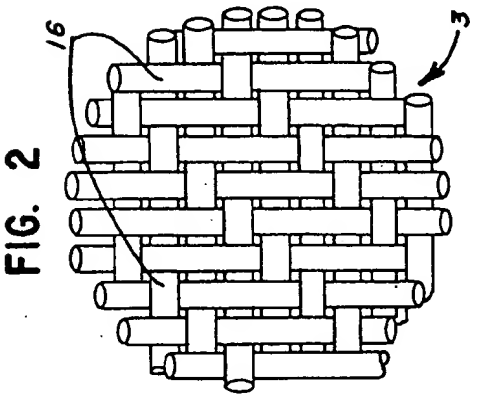
FIG. 2
16
3

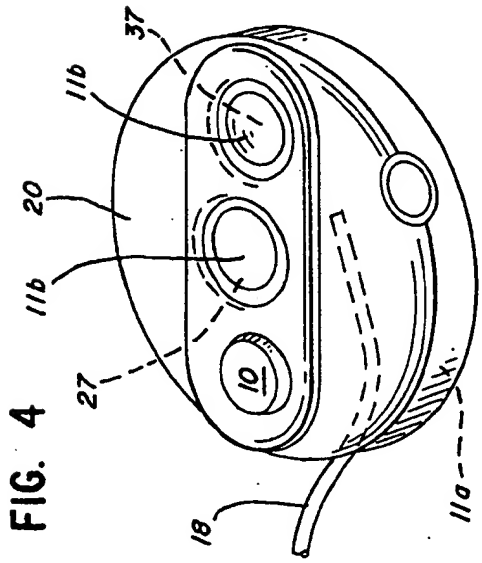
FIG. 4
37
11b
20
11b
27
10
18
11a

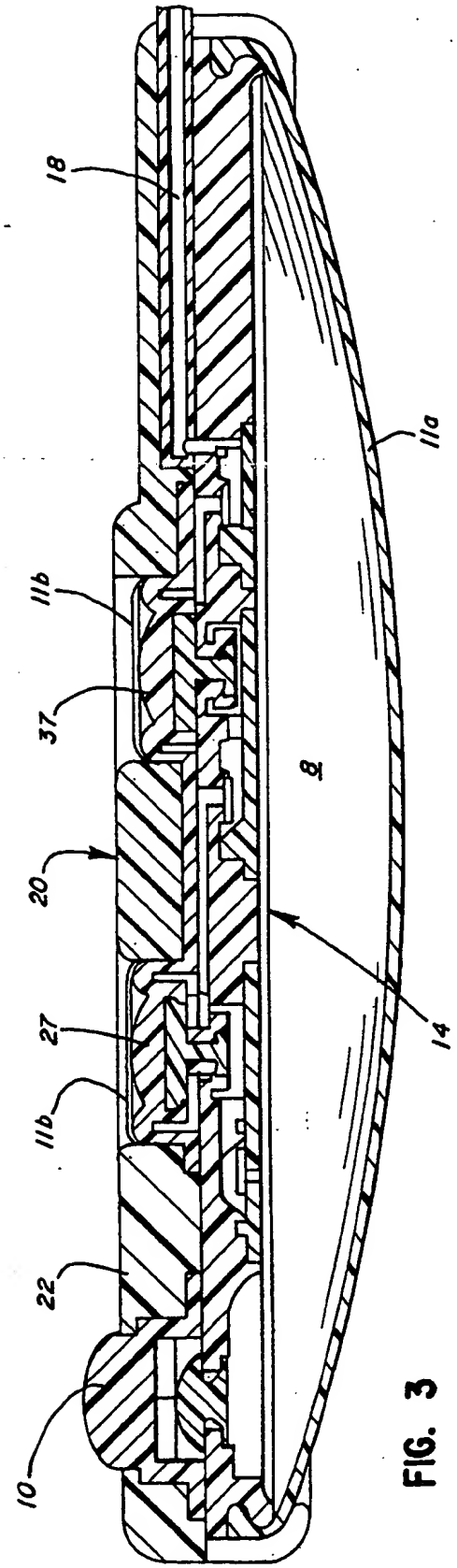
FIG. 3
18
11a
11b
37
8
20
14
27
11b
22
10